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March 14, 2016

Jennifer LaPoma
U.S. Environmental Protection Agency (USEPA)
Region II Headquarters
290 Broadway, 19th Floor East
New York, NY 10007-1866

Re: Passaic River Study Area – 17 Mile Project
Newark City, Essex
SRP PI# 332799
Activity Number Reference: RPC030001

Dear Ms. LaPoma:

As discussed between Anne Hayton of the New Jersey Department of Environmental Protection (NJDEP) and you on March 11, 2016, the NJDEP reviewed portions of Section 7, the Uncertainty Section, of the Draft Baseline Human Health Risk Assessment (BHHRA) dated December 2015. Section 7 of the BHHRA was reviewed specifically for how dioxin toxicity and assessment are presented. Based on this review, two additional areas in need of revision have been identified for consideration by the USEPA. These areas include the discussion of dioxin toxicity in Sections 7.3.1 and 7.3.2, and the discussion of dioxin TEFs in Section 7.3.3. In both cases, presentation in these sections are observed to: a. over-emphasize areas of potential uncertainty, and b. simultaneously omit relevant information for a particular topic of focus. The NJDEP submitted comments to the USEPA last month (NJDEP letter dated February 24, 2016) regarding the review of the Draft BHHRA, December 2015. Based on this recent review, the NJDEP would like the USEPA to consider these additional comments below.

1. Section 7.3.2, page 7-34, last paragraph, provided below, states:

"Much of the knowledge about the health effects of TCDD and other DLCs in humans comes from studies of relatively highly exposed populations in the workplace and through the use of the herbicide Agent Orange in the Vietnam War. The potential adverse effects of TCDD and DLCs from long-term, low-level exposures to the general public are not directly observable and remain controversial. To complicate matters, experimental data from animal bioassays similarly reflect effects associated with much higher exposure to TCDD and related compounds than would be expected in the general environment. Estimating risks from the doses employed in the studies to typical human exposure levels require making assumptions about the point at which adverse effects are considered to occur (point of departure), methods for modeling the effects at doses below this point (linear vs. nonlinear extrapolation), the relationship of the doses in animals to the concentrations in humans (scaling vs. physiologically based pharmacokinetic modeling), and the relationship of the observed effects to mixtures of these compounds in the environment, among others. NRC's review of USEPA's proposed

Reassessment (USEPA 2003c) suggests some of EPA's assumptions, such as the decision to rely solely on a default linear model for low dose extrapolation, lack adequate scientific support (NRC 2006). As previously noted, USEPA is revising the Reassessment document to include alternative approaches and a more thorough discussion of uncertainty."

NJDEP Comment: Although Section 7.3.2 addresses *carcinogenic* dose-response information, some observations by the NJDEP include the following:

a. The opening sentence should specify "carcinogenic health effects", since a similar dioxin-focus paragraph is not provided in Section 7.3.1, noncarcinogenic dose-response. If not revised as recommended, much of the cited paragraph could be inadvertently misleading with regard to the state of the science on TCDD human toxicity for noncarcinogenic effects, as described below. However, if comment 1b below is addressed, the recommended revision may not be necessary.

b. Section 7.3.1, Noncarcinogenic dose-response – Given that human health risks associated with the 17-Mile Study Area are largely attributable to TCDD and dioxin-like compounds (DLCs), Section 7.3.1 should be amended to add specific information on the Feb 2012 chronic oral RfD used for this class of contaminants. It should be noted that despite uncertainties described in this section, strong information exists for TCDD, an important risk-driver contaminant for this project. The published chronic oral RfD for 2,3,7,8-TCDD is supported by two epidemiology studies (Mocarelli et al., 2008 and Baccarelli et al., 2008) showing co-critical effects involving impairments in neurological and reproductive development, respectively. In addition, based on these studies ***and*** supporting information from other studies (refer to Section I.A.4 of IRIS Feb 2012 RfD for TCDD), the "confidence" in the published TCDD chronic oral RfD is listed as "High" (refer to Section I.A.5 of IRIS Feb. 2012 RfD for TCDD). This information should be included to add appropriate perspective and balance to Section 7, the uncertainty section.

Recommendation: Revision of the BHHRA paragraph cited above is recommended to *clarify* that the dioxin-focus paragraph in Section 7.3.2 is specific to carcinogenic dose response information. In addition, dioxin-focus information (as discussed in comment 1b above) should be added in Section 7.3.1, non-carcinogenic dose response, because a greater level of confidence in these health effects now exists.

2. Section 7.3.3, TEF Approach, entire section.

NJDEP Comment: Nearly 5 pages of the uncertainty section are devoted to discussing the TCDD TEQ approach (USEPA 2010) as applied to dioxin and PCB data for this project. It is agreed that areas of uncertainty exist within the TCDD TEQ Approach. However, missing from the text is the acknowledgement that since its inception, this approach:

- Has been the focus of intensive scientific scrutiny
- Has been improved and strengthened over the years by incorporating newer scientific studies as they became available and through World Health Organization (WHO) consensus regarding congener-TEF assignments provided by leading experts regarding toxicity of dioxin and dioxin-like compounds (DLCs)
- In current form, is considered standard practice nationally and internationally for use in risk assessments involving dioxin and DLCs

In short, the TCDD TEQ Approach has substantial scientific standing and is considered the best tool available for assessment of dioxins and DLCs in CERCLA risk assessments.

Recommendation: At a minimum, the opening paragraph and conclusion of Section 7.3.3 must affirmatively acknowledge the validity and applicability of the TCDD TEQ Approach for use in the subject BHHRA.

Please incorporate these comments into the letter that the USEPA will be sending to the Cooperating Party Group.

Thank you for your cooperation in this matter. If you have any questions, please call me at (609) 633-1448, or email at Jay.Nickerson@dep.nj.gov.

Sincerely,

Jay Nickerson
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Site Remediation Program
New Jersey Department of Environmental Protection

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